

## CHAPTER 3.1.5.

### INFECTION WITH *MARTEILIA REFRINGENS*

#### Article 3.1.5.1.

The disease agent is *Marteilia refringens*.

#### Article 3.1.5.2.

##### **Susceptible and vector species**

- 1) Naturally susceptible species in which clinical signs of infection with *Marteilia refringens* are known to develop are: European flat oyster (*Ostrea edulis*), Australian mud oyster (*Ostrea angasi*), Argentinean oyster (*Ostrea puelchana*) and Chilean flat oyster (*Ostrea chilensis*).

*Marteilia refringens* can cause [asymptomatic] subclinical infection in [the] these susceptible species [listed in Article 3.1.5.2].

- 2) Experimental infections have not been reported in other species.

- 3) The Pacific oyster, *Crassostrea gigas*, is not regarded to be a vector of *Marteilia refringens*

[Article 3.1.5.3.

*Marteilia refringens* can cause asymptomatic infection in the susceptible species listed in Article 3.1.5.2.

Article 3.1.5.4.

Infections with *Marteilia* spp. of unclear taxonomic affiliation have been described in the following species: common edible cockle (*Cerastoderma* [*Cardium*] *edule*), blue mussel (*Mytilus edulis*), Mediterranean mussel (*Mytilus galloprovincialis*), giant clam (*Tridacna maxima*) and calico scallop (*Argopecten gibbus*).

Article 3.1.5.[5]3.

Suspect cases of natural infection with *Marteilia refringens* in species other than those listed in Article[s] 3.1.5.2 [and 3.1.5.3] should be referred immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article 3.1.5.[6]4.

Methods for surveillance, diagnosis and confirmatory identification of *Marteilia refringens* are provided in the *Aquatic Manual*.

Article 3.1.5.[7]5.

##### ***Marteilia refringens* free country**

A country may be [considered] officially declared free from *Marteilia refringens* if it meets the conditions in [Articles 3.1.5.8 or 3.1.5.9] point 1) or 2) or 3) below.

If a country shares water bodies of coastal areas with one or more other countries, it can only be declared a *Marteilia refringens* free country if all the shared coastal areas are declared *Marteilia refringens* free zones (see [Articles 3.1.5.10 to 3.1.5.12] Article 3.1.5.6).

[ Article 3.1.5.8. ]

- 1) A country where none of the susceptible species listed in Article 3.1.5.2 is present [or where there has never been any observed occurrence of] and where no abnormal mortalities have been caused by infection

with *Marteilia refringens* [despite conditions that are conducive to its clinical expression] in other species for at least the past 25 years, according to the methods described in Chapter 3.1.3 of the Aquatic Manual, may be officially declared [considered] free from [infection with] *Marteilia refringens* when [prescribed biosecurity] basic disease security conditions have been in place continuously in the country for at least the previous [2] 10 years and infection is not known to be established in wild populations; [as follows:

- 1) infection with *Marteilia refringens* is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- 2) an *early detection system* is in place within the country enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant infections, and training of veterinarians or mollusc health specialists in detecting and reporting unusual infection occurrence; and
- 3) infection is not known to be established in wild populations; and
- 4) conditions applied to imports to prevent the introduction of *Marteilia refringens* (e.g. live molluscs introduced for aquaculture purposes or for human consumption) into the country are in place (see Section 1.4).]

OR

- 2) A country where the susceptible species listed in Article 3.1.5.2 are present and where there has never been any observed occurrence of infection with *Marteilia refringens* for at least the past 25 years despite conditions that are conducive to its clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.3 of the Aquatic Manual, may be officially declared [considered] free from *Marteilia refringens* when basic disease security conditions have been in place continuously in the country for at least the previous 10 years and infection is not known to be established in wild populations;

[ Article 3.1.5.9. ]

OR

- 3) A country where the last known occurrence was within the previous 25 years or where the infection status prior to targeted surveillance was [previously] unknown, for example because of the absence of conditions conducive to clinical expression of the infection, as described in Chapter 3.1.3 of the Aquatic Manual, may be officially declared [considered free] from *Marteilia refringens* when:
  - a) it meets [the prescribed biosecurity] basic disease security conditions [detailed in Article 3.1.5.8]; and
  - b) targeted surveillance as described in Chapters 1.4 and 3.1.3 in the *Aquatic Manual* has been in place for at least the past 2 years for susceptible species listed in Article 3.1.5.2 in *aquaculture establishments* or wild populations without detection of [the disease agent listed in Article 3.1.5.1] *Marteilia refringens*.

Article 3.1.5.[10]6.

### ***Marteilia refringens* free zone**

A zone free of infection with *Marteilia refringens* may be established and officially declared within the *territory* of one or more countries of infected or unknown status for *Marteilia refringens* if the *zone* meets the conditions referred to in [Articles 3.1.5.11 or 3.1.5.12] point 1) or 2) or 3) below. Such *Marteilia refringens* free *zones* must comprise: one or more entire water body of coastal area(s) defined on the basis of the distribution of the susceptible species listed in Article 3.1.5.2, geographical and hydrographical criteria. Such *zones* must be clearly delineated on a map of the *territory* of the country(ies) concerned by the *Competent Authority*.

If a *zone* extends over more than one country, it can only be declared a *Marteilia refringens* free *zone* if the conditions outlined below apply to all [shared] areas of the *zone*.

[Article 3.1.5.11.]

1) In a country of unknown status for *Marteilia refringens*, a zone where none of the susceptible species listed in Article 3.1.5.2 is present [or where there has never been any observed occurrence of] and where no abnormal mortalities have been caused by infection with *Marteilia refringens* in other species [despite conditions that are conducive to its clinical expression] for at least the past 25 years, according to the methods described in Chapter 3.1.3 of the *Aquatic Manual*, may be *officially declared* [considered] free from [infection with] *Marteilia refringens* when [prescribed biosecurity] *basic disease security conditions* have been in place continuously in the zone for at least the previous [2] 10 years and infection is not known to be established in wild populations; [as follows:

- 1) infection with *Marteilia refringens* is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- 2) an *early detection system* is in place within the zone enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant infections, and veterinarians or molluscs health specialists are trained in detecting and reporting unusual disease occurrence; and
- 3) infection is not known to be established in wild populations; and
- 4) official control measures to prevent the introduction of *Marteilia refringens* (e.g. live molluscs introduced for aquaculture purposes or for human consumption) into the zone are in place]

OR

2) In a country of unknown status for *Marteilia refringens* a zone where the susceptible species listed in Article 3.1.5.2 are present and where there has not been any observed occurrence of infection with *Marteilia refringens* for at least the past 25 years despite conditions that are conducive to its clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.3 of the *Aquatic Manual*, may be *officially declared* [considered] free from *Marteilia refringens* when *basic disease security conditions* have been in place continuously in the zone for at least the previous 10 years and infection is not known to be established in wild populations;

[ Article 3.1.5.12.]

OR

3) A zone where the last known occurrence was within the previous 25 years or where the infection status prior to *targeted surveillance* was [previously] unknown, for example because of the absence of conditions conducive to clinical expression, including gross signs and abnormal mortality, of the infection as described in Chapter 3.1.3 of the *Aquatic Manual*, may be *officially declared* [considered] free from *Marteilia refringens* when:

- a) it meets [the prescribed biosecurity] *basic disease security conditions* [detailed in Article 3.1.5.11]; and
- b) *targeted surveillance* as described in Chapters 1.4 and 3.1.5 in the *Aquatic Manual* has been in place for at least the past 2 years for the susceptible species listed in Article 3.1.5.2 in *aquaculture establishments* or wild populations without detection of [the disease agent listed in Article 3.1.5.1] *Marteilia refringens*.

These provisions also apply if the zone to be *officially declared* free lies in an *Marteilia refringens*-infected country.

[ Article 3.1.5.13.]

#### ***Marteilia refringens* free aquaculture establishment**

An *aquaculture establishment* free of infection with *Marteilia refringens* may be located within an *Marteilia refringens* infected country or zone or within a country or zone of unknown status with respect to *Marteilia refringens* if it meets the conditions referred to in Articles 3.1.5.14 or 3.1.5.15.

Such *aquaculture establishments* free of infection with *Marteilia refringens* must be supplied by a contained water source (e.g. a well, borehole, closed recirculation system, etc.) in which the culture system water cannot be contaminated by the disease agent, and be inaccessible to susceptible species or potential carriers from the natural environment.

Article 3.1.5.14.

An *aquaculture establishment* where none of the susceptible species listed in Article 3.1.5.2 is present or where there has never been any observed occurrence of infection with *Marteilia refringens* despite conditions that are conducive to its clinical expression may be considered free from infection with *Marteilia refringens* when *prescribed biosecurity conditions* have been in place continuously in the *aquaculture establishment* for at least the previous 2 years as follows:

- 1) infection with *Marteilia refringens* is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- 2) the *aquaculture establishment* complies with an *early detection system* enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant infections, and the staff are trained in detecting and reporting unusual disease occurrence; and
- 3) infection is not known to be established in wild populations; and
- 4) official control measures to prevent the introduction of *Marteilia refringens* into the *aquaculture establishment* are in place.

Article 3.1.5.15.

An *aquaculture establishment* where the last known occurrence of infection with *Marteilia refringens* was within the previous 25 years or the infection status was previously unknown, for example because of the absence of conditions conducive to clinical expression, may be considered free from infection with *Marteilia refringens* when:

- 1) it meets the *prescribed biosecurity conditions* detailed in Article 3.1.5.14; and
- 2) *targeted surveillance* as described in chapters 1.4 and 3.1.5 in the *Aquatic Manual* has been in place for at least the past 2 years without detection of the disease agent listed in Article 3.1.5.1.]

Article 3.1.5.[16]7.

### **Maintenance of free status**

A country or zone [or *aquaculture establishment*] that is [considered] officially declared free from [infection with] *Marteilia refringens* following the provisions of [Articles 3.1.5.8, 3.1.5.11 and 3.1.5.14] point 1) or 2) of Articles 3.1.5.5 or 3.1.5.6, respectively, may maintain its official status [as free from infection with *Marteilia refringens*] provided that [the prescribed biosecurity] basic disease security conditions are continuously maintained.

A country or zone [or *aquaculture establishment*] that is [considered] officially declared free from [infection with] *Marteilia refringens* following the provisions of [Articles 3.1.5.9, 3.1.5.12 and 3.1.5.15] point 3) of Articles 3.1.5.5 or 3.1.5.6, respectively, may discontinue targeted surveillance and maintain its official status as free from [infection with] *Marteilia refringens* provided that [*targeted surveillance* is continued at a level commensurate with the degree of risk assessed by the *Competent Authority*] conditions that are conducive to clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.5 of the Aquatic Manual, exist and country/zone disease security conditions are continuously maintained.

However, for officially declared free zones in infected countries and in all cases where conditions are not conducive to clinical expression, including gross signs and abnormal mortality, targeted surveillance will need to be continued, but at a level commensurate with the degree of risk assessed by the Competent Authority.

Article 3.1.5.[17]8.

### **Suspension and restoration of free status**

If a *Competent Authority* has reason to believe that any of the conditions for [recognition of country, zone or *aquaculture establishment* freedom] maintaining official status as a *Marteilia refringens* free country or zone has been breached, it should immediately suspend the free status, implement any necessary containment measures and conduct an investigation.

If the investigation confirms that the suspected breach has not taken place, free status may be restored.

If the investigation confirms that the suspected breach has taken place, suspension of free status is continued. The *Competent Authority* should carry out an epizootiological investigation to determine the likelihood of *Marteilia refringens* entry and establishment [and re-establish the conditions in Articles 3.1.5.7. to 3.1.5.9, 3.1.5.10. to 3.1.5.12, or 3.1.5.13. to 3.1.5.15 if *Marteilia refringens* free status is to be restored]. If this investigation concludes that disease entry and establishment have not occurred, free status may be officially restored.

If the investigation confirms a significant likelihood that disease entry and establishment have occurred, the *Competent Authority* must declare that the free status is lost. In order to restore *Marteilia refringens* free status, the conditions in Articles 3.1.5.5 or 3.1.5.6 must be complied with again in full. Steps leading to re-establishment of free status may require depopulation, *fallowing*, *disinfection* and other measures, as described in Section 1.6, as well as *zoning* as described in Section 1.4.

Article 3.1.5.[18]2.

When importing live molluscs of [any age group] the susceptible species listed in Article 3.1.5.2 for re-immersion, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of a surveillance scheme conducted according to the procedures described [above] in Articles 3.1.5.5 or 3.1.5.6 (as applicable), whether or not the place of production of the consignment is a country or zone [or *aquaculture establishment*] officially declared free from [infection with] *Marteilia refringens*

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Aquatic Code*

Article 3.1.5.[19]10.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 3.1.5.9, or cannot certify the place of production of the consignment as being free from [infection with] *Marteilia refringens*, the *importing country* should assess the risks of introduction and establishment of *Marteilia refringens* associated with the importation of live molluscs of the species listed in Article 3.1.5.2 from the *exporting country*, or seek assurance from the *exporting country* that *basic disease security conditions* are met, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Article 2.1.1.11.

When importing live molluscs of species other than those listed as susceptible in Article 3.1.5.2, the *Competent Authority* of the *importing country* should assess the risk of introduction and establishment of *Marteilia refringens* associated with the importation prior to a decision on whether to authorise the importation, taking into account, for example, whether there is evidence for or against the presence of *Marteilia refringens* in the place of origin. This assessment should be made available to the *exporting country*.

The *international aquatic animal health certificate* may not be required for mollusc species that have been demonstrated not to be vectors of *Marteilia refringens* and listed in Article 3.1.5.2, even if the molluscs originate from an infected country or zone.

Article 3.1. 5.[20]12.

When importing live molluscs of [of commercial size] the species listed as susceptible in Article 3.1.5.2 destined for human consumption, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of a surveillance scheme conducted according to the procedures described [above and detailed in the *Aquatic Manual*] in Articles 3.1.5.5 or 3.1.5.6 (as applicable), whether or not the place of production of the consignment is a country or zone [or aquaculture establishment] *officially declared free from *Marteilia refringens**.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Aquatic Code*. This certificate may not be required if the imported molluscs are destined for:

- 1) direct human consumption without any re-immersion, or
- 2) storage, during a short period before consumption, in tanks or holding facilities that ensure isolation from the local environment and avoid the potential introduction of *Marteilia refringens*

Article 3.1. 5.[21]13.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 3.1.5.12, or cannot certify the place of production of the consignment as being free from [infection with] *Marteilia refringens*, the *importing country* should assess the risks of introduction and establishment of *Marteilia refringens* associated with the importation [of molluscs of commercial size destined for human consumption] from the *exporting country* of molluscs of the species listed as susceptible in Article 3.1.5.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Rather than refusing such imports, the *importing country* may opt to manage these *risks*, if the consignment is destined for:

- 1) direct human consumption without any re-immersion, or
- 2) storage, during a short period before consumption, in tanks or holding facilities that ensure isolation from the local environment and avoid the potential introduction of *Marteilia refringens*.

Article 3.1. 5.14.

When importing live molluscs of species other than those listed in Article 3.1.5.2, the *importing country* should assess the risk of introduction and establishment of *Marteilia refringens* associated with the importation prior to a decision on whether to authorise the importation. This assessment should be made available to the *exporting country*.

Article 3.1. 5.[22]15.

The *Competent Authorities* of *exporting countries* should not authorise the exportation of live *molluscs* from populations known to be infected with *Marteilia refringens* without the [full] prior agreement of the *importing country*.